REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1-15, 27, 29, 38, 40 and 42-50 presently appear in this application, with claims 42-50 newly added, and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

The personal interview on September 19, 2007, among Roger Browdy and Allen Yun, representing applicant, and Examiners Ballard and Kemmerer is hereby gratefully acknowledged. Applicant's representatives wish to thank the examiners for the courtesies extended during this interview. The amended set of claims, including the new claims 42-50, were discussed at the interview with regard to the prior art rejections and the obviousness-type double patenting rejections. The arguments presented at the interview are incorporated herein.

Claims 1-3, 5-10, 15, 23-25, 28, 30-34 and 41 have been provisionally rejected under the doctrine nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 6, 10, 16-17 and 21-24 of copending application no. 10/481,642. The examiner states that the claims of copending application '642 are directed to an antigenic

product comprising an antigenic peptide "that comprises an epitope of a deposit-forming polypeptide involved in plaque-forming disease or disorder" and takes the position that the entire AβPP molecule comprises amyloid β, and accordingly, AβPP would comprise an epitope of a deposit-forming polypeptide involved in plaque-forming disease or disorder (i.e., amyloid β). This rejection is respectfully traversed.

MPEP 804 II states:

> Domination and double patenting should not be confused. They are two separate issues. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application. Domination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection. *In re Kaplan*, 789 F.2d 1574, 1577-78, 229 USPQ 678, 681 (Fed. Cir. 1986); and *In re Sarrett*, 327 F.2d 1005, 1014-15, 140 USPQ 474, 482 (CCPA 1964). However, the presence of domination does not preclude double patenting. See, e.g., *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968).

This situation is applicable here. The present invention is directed to antigenic peptides that have a sequence from AβPP that spans the β-secretase cleavage site of AβPP and to immunizing compositions comprising a display vehicle displaying the antigenic peptides which induce an immune

response against the β-secretase cleavage site of AβPP to block β-secretase cleavage of AβPP. The invention of copending application '642 is directed to antigenic products that display epitopes of deposit-forming polypeptide such as amyloid β. Accordingly, the claims of '642 only superficially overlap with the instant claims because the antigenic peptide recited in '642 may optionally include residues other than, e.g., those in an epitope of amyloid β. Likewise, the antigenic peptide recited in the instant claims may optionally include the EFRH epitope of amyloid β that is a preferred amyloid β epitope in '642. However, both are primarily directed to different epitopes, amyloid β versus the β-secretase cleavage site which is not present in amyloid β.

Just because the scope of the claims in '642 overlaps with the scope of the instant claims does not mean that the instant claims are obvious over the claims of '642. One of ordinary skill in the art would not be motivated to specifically include residues from the β-secretase cleavage site of AβPP that are not present in amyloid β in an antigenic peptide when the goal of '642 is to elicit an immune response against the amyloid β target, not the β-secretase cleavage of AβPP.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claims 11, 12 and 14 have been provisionally rejected under the doctrine of nonstatutory obviousness-type double patenting over claims 1, 3 and 10 of copending application 11/073,526. The examiner states that this is similar to the situation above with respect to '642 because the polypeptide displayed on the virus particle comprises at least one epitope of amyloid β. This rejection is respectfully traversed.

Similar to the argument presented above, '526 is directed to a virus particle displaying a peptide which includes epitopes of amyloid β to induce an immune response to amyloid β. Such a virus particle may optionally include other residues besides those in an epitope of amyloid β. However, any such additional residues would include the β-secretase cleavage site merely by coincidence and not by design. Thus, one of ordinary skill in the art would not be motivated to specifically include residues from the β-secretase cleavage site in AβPP that are not present in amyloid β on a virus particle (to be displayed with the amyloid β epitope) when the goal of '526 is to elicit an immune response against the amyloid β target, not the β-secretase cleavage site of AβPP.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claims 1 and 15 have been rejected under 35 U.S.C. §102(e) as being anticipated by Srivastava, WO 01/53457, as evidenced by Vassar et al., *Science* 286:735-741 (1999). This rejection is obviated by the amendment to claim 1 to recite a display vehicle. New claim 44, and claims dependent therefrom, are not subject to this rejection because of the recitation that the antigenic peptide consists of 6-14 residues, as supported in the present specification at page 24, middle of paragraph [0061].

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claims 1-11, 13-15, 23-26, 28, 30-35, 37, 39 and 41 have been rejected under 35 U.S.C. §102(b) as being anticipated by Schenk et al., WO 00/72880. The examiner states that the 104 residue pBx-6 polypeptide taught by Schenk would comprise an AβPP epitope spanning the β-secretase cleavage site and that the shorter antigenic peptide fragments taught in Schenk's Figs. 19 and 20 comprise the β-secretase cleavage site of AβPP. This rejection is respectfully traversed.

The 104 residue pBx6 polypeptide disclosed in Schenk is not displayed on a display vehicle as presently recited in

the claims. New claims 44-50 to the antigenic peptide recite that it consists of 6-14 residues and therefore the 104 residue pBx6 polypeptide does not anticipate the new antigenic peptide claims 44-50.

Regarding the peptide fragments disclosed in Schenk's Figs. 19 and 20, a closer reading of the disclosure in Schenk on page 102 relating to the epitope mapping experiment shown in Figs. 19 and 20 clearly shows that the peptides of Figs. 19 and 20 also have a GGK linker and are biotinylated. The GGK linker and biotin moiety on the biotinylated peptide are bound to streptavidin coated wells of 96 well plate. Accordingly, the GGK linker, biotin moiety and 96 well plate cannot be construed to be a display vehicle as recited in the present claims because it certainly cannot serve as an immunizing composition for administration to a patient. Therefore, Schenk's shorter peptide fragments cannot anticipate the present claims. New claims 44-50 to an antigenic peptide consisting of 6-14 residues also cannot be anticipated by Schenk's biotinylated peptide.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 11, 12 and 36 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Schenk et al., WO 00/72880 in view of Frenkel et al., *Proc. Natl. Acad. Sci.*

USA, 97(21):11455-11459 (2000). This rejection is respectfully traversed.

The 104 residue AβPP polypeptide (which is part of the pBx6 fusion protein), when used as an immunogen to immunize PDAPP transgenic mice, did not demonstrate any significant changes in Aβ or AβPP levels, contrary to what was observed using Aβ specific immunogens (see the paragraph bridging pages 64 and 65). As no significant treatment-associated changes in Aβ or AβPP levels were observed from immunizing with a 104 residue region of AβPP spanning the β-secreatase cleavage site, Schenk's experimental results serve as a teaching away from using or displaying an antigenic peptide that spans the β-secretase cleavage site in an immunizing composition. Accordingly, one of ordinary skill in the art would not be led to arrive at the presently claimed invention by the combination of Schenk's and Frenkel's teachings.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claim 35 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is made moot by the cancellation of claim 35 without prejudice.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting

their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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